



An Overview of the U.S. Medical Devices and Biopharmaceutical Industries

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Introduction

The United States is one of the largest markets for both [medical devices](#) and [biopharmaceuticals](#) in the world. Both industries have a large impact on the U.S. economy and support hundreds of thousands of jobs, according to the U.S. Census Bureau.

This report provides investors with an overview of greenfield investment opportunities in the United States by highlighting key trends in the U.S. Medical Devices and Biopharmaceutical industries, as well as both industries' primary customer: the Local Health Services industry. The goal of this report is to provide a broad picture of these industries in the United States by compiling data from various sources. As industry definitions vary by source, this report attempts to provide similar data across sources wherever possible; in some cases, the closest possible industry match has been provided. This report also compiles resources on the relevant U.S. regulatory agencies for both industries.

Definitions of key terms may be found at the end of the report. Key highlights from the report include:

- In 2020, the Medical Devices industry employed over 329,000 people and had an annual payroll of approximately \$25.8 billion in the United States. The Biopharmaceuticals industry employed over 224,000 people and had an annual payroll of approximately \$21.2 billion.
- Of the subsectors of the Medical Devices industry, Surgical and Medical Instrument Manufacturing had the highest sales, value of shipments, or revenue (approximately \$36.3 billion) in 2020. Of the subsectors of the Biopharmaceuticals industry, Pharmaceutical Preparation Manufacturing had the highest sales, value of shipments, or revenue (approximately \$154.7 billion) in 2020.
- When looking specifically at the impact of foreign direct investment (FDI) in these industries, majority foreign-owned companies in the United States directly supported 107,200 U.S. jobs in the Medical Equipment and Supplies Manufacturing industry and 215,100 jobs in the Pharmaceuticals and Medicines Manufacturing industry in 2019.

Medical Devices

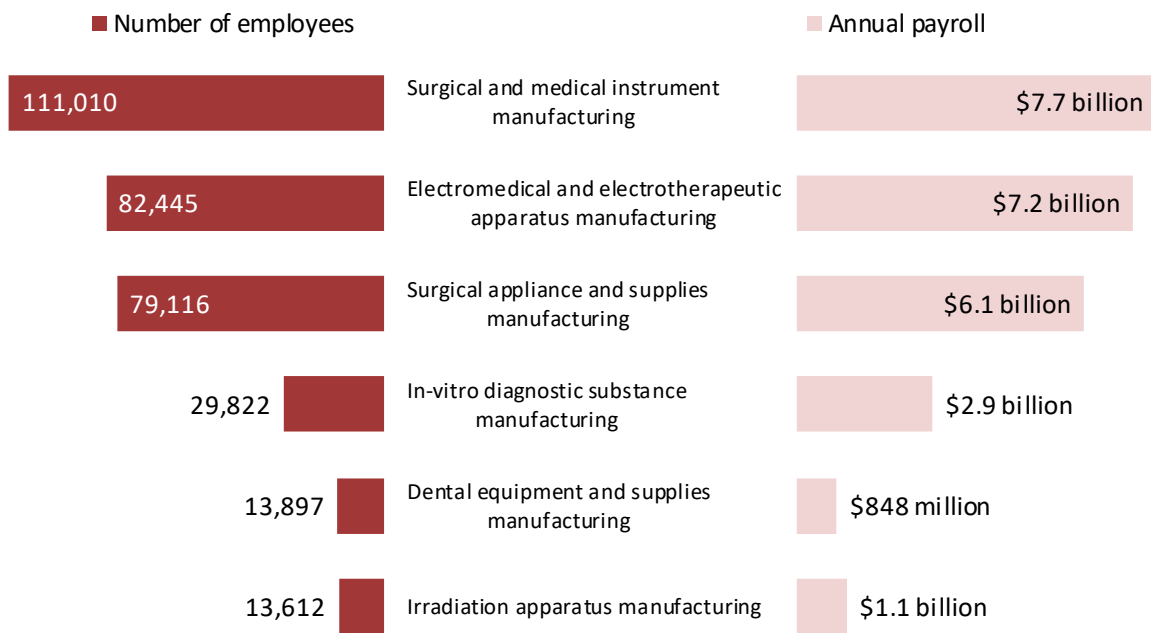
The Medical Devices industry includes a variety of subsectors as categorized under the North American Industry Classification System (NAICS). Based on definitions from the U.S. Economic Development Administration and the U.S. International Trade Administration's Office of Health and Information Technologies, this section focuses on the subsectors of:

- Surgical and Medical Instrument Manufacturing (NAICS 339112)
- Surgical Appliance and Supplies Manufacturing (NAICS 339113)
- Dental Equipment and Supplies (NAICS 339114)
- In-Vitro Diagnostic Substance Manufacturing (NAICS 325413)
- Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334510)
- Irradiation Apparatus Manufacturing (NAICS 334517)

The U.S. Census Bureau’s [Annual Survey of Manufactures \(ASM\)](#) provides sample estimates of statistics for all U.S. manufacturing establishments with one paid employee or more. The ASM provides the best measure of current U.S. manufacturing industry outputs, inputs, and operating status.

Figure 1 presents the number of employees and the annual payroll for each of the Medical Devices subsectors in 2020. In 2020, the Medical Devices industry employed over 329,000 people and had an annual payroll of approximately \$25.8 billion. Of these six subsectors, Surgical and Medical Instrument Manufacturing had the most employees (111,010) and the highest annual payroll (\$7.7 billion).

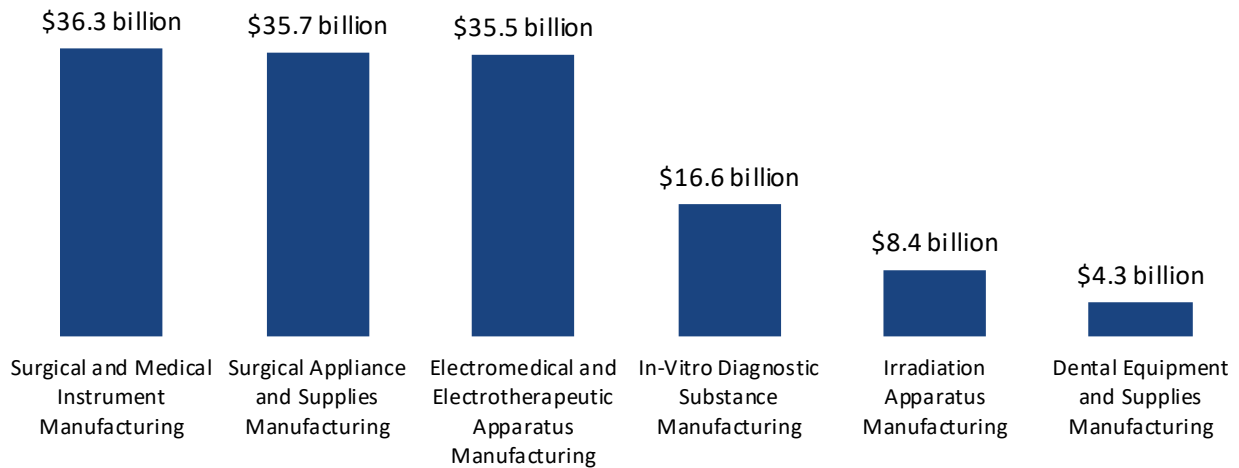
Figure 1: Employment and Payroll for Medical Devices Subsectors, 2020



Source: [U.S. Census Bureau, Annual Survey of Manufactures](#)

Figure 2 shows the sales, value of shipments, or revenue for each of the Medical Devices subsectors in 2020. Sales, value of shipments, or revenue is a measure of economic output for all appropriate dollar volume measures during the census year. Surgical and Medical Instrument Manufacturing had the highest sales, value of shipments, or revenue (approximately \$36.3 billion), followed by Surgical Appliance and Supplies Manufacturing (\$35.7 billion).

Figure 2: Sales, Value of Shipments, or Revenue for Medical Devices Subsectors, 2020



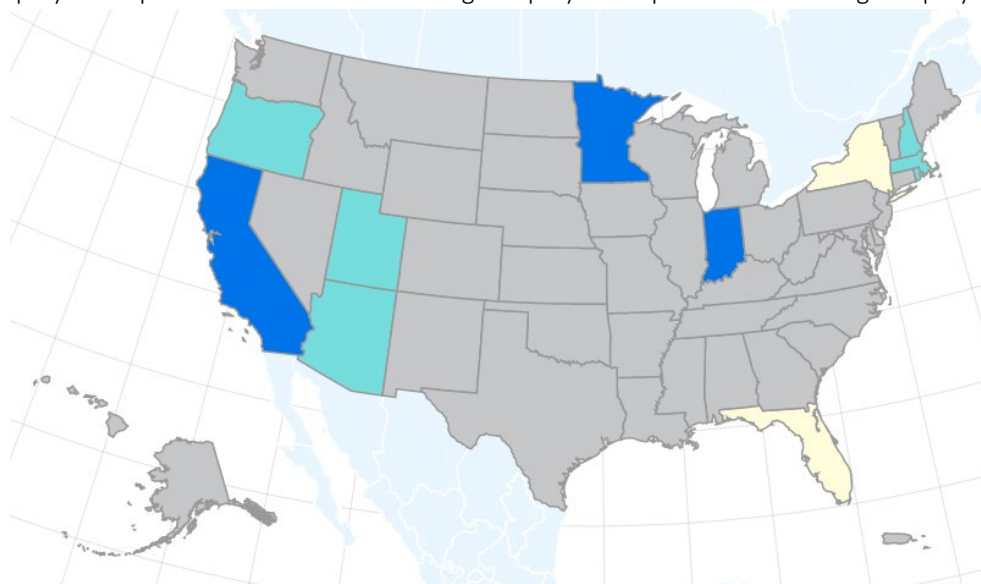
Source: [U.S. Census Bureau, Annual Survey of Manufactures](#)

The U.S. Cluster Mapping Tool presents information on the states in which the Medical Devices industry has particularly strong clusters. The resource’s definition of the Medical Devices cluster differs slightly from the definition used in this report, specifically focusing on subsectors related to optical instruments and ophthalmic goods as well as surgical and dental instruments and supplies. In 2019, the Medical Devices cluster was made up of 4,465 establishments across the United States that employed 260,735 professionals earning an average annual wage of \$75,655.

Figure 3 presents the states that offer high employment specialization and share in the Medical Devices cluster. The states that offer both high employment specialization and share in the cluster are California, Indiana, and Minnesota.

Figure 3: Employment Specialization and Share in the Medical Devices Cluster by State, 2019

■ High Employment Specialization and Share ■ High Employment Specialization ■ High Employment Share



Source: [U.S. Cluster Mapping](#)

Figure 4 presents the establishments, employment, and location quotient for the three states that offer high employment specialization and share in the Medical Devices cluster. Of these states, Minnesota has the highest location quotient (2.74), while California has the most employees (49,109) and establishments (767). California, Indiana, and Minnesota all have a location quotient value greater than 1, which indicates a higher than average cluster concentration in these three states.

Figure 4: Employment and Establishments in the Medical Devices Cluster for States with High Employment Specialization and Share, 2019

State	Location Quotient	Employment	Establishments
Minnesota	2.74	15,203	182
Indiana	2.67	15,829	127
California	1.56	49,109	767

Source: [U.S. Cluster Mapping](#)

For more information on the Medical Devices cluster, more granular data (including data specifically on the Optical Instruments and Ophthalmic Goods subcluster as well as the Surgical and Dental Instruments and Supplies subcluster) is available on the [U.S. Cluster Mapping Tool's website](#).

Foreign Direct Investment in Medical Devices

The U.S. Bureau of Economic Analysis (BEA) provides data on foreign direct investment (FDI) in the United States. The most granular data available through BEA related to the Medical Devices industry is for the Medical Equipment and Supplies industry (NAICS 3391, which represents subsectors including but not limited to some of the Medical Devices subsectors).

The inward FDI position for the Medical Equipment and Supplies industry was \$107.2 billion in 2020. In addition, majority foreign-owned companies in the United States directly supported 107,200 U.S. jobs in the Medical Equipment and Supplies Manufacturing industry as of 2019.

According to fDi Markets (a service of the *Financial Times* that monitors greenfield cross-border investments), companies announced 116 greenfield foreign direct investment (FDI) projects in the United States in the Medical Devices sector from December 2016 to November 2021. These projects had an estimated capital expenditure of \$2.0 billion and were expected to create 8,218 jobs.

Biopharmaceuticals

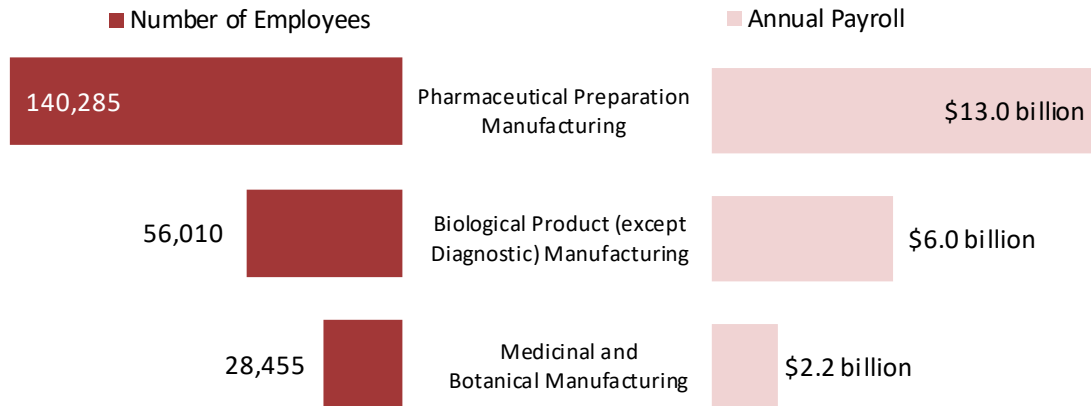
The Biopharmaceuticals industry represents a variety of businesses. For the purposes of this report, the industry is defined as including the following subsectors:

- Medicinal and Botanical Manufacturing (NAICS 325411)
- Pharmaceutical Preparation Manufacturing (NAICS 325412)
- Biological Product (except Diagnostic) Manufacturing (NAICS 325414)

Figure 5 presents the number of employees and the annual payroll for each of the Biopharmaceuticals industry subsectors in 2020. In 2020, the Biopharmaceuticals industry employed over 224,000 people and

had an annual payroll of approximately \$21.2 billion. Of the three subsectors, Pharmaceutical Preparation Manufacturing had the most employees (140,285) and the highest annual payroll (\$13.0 billion).

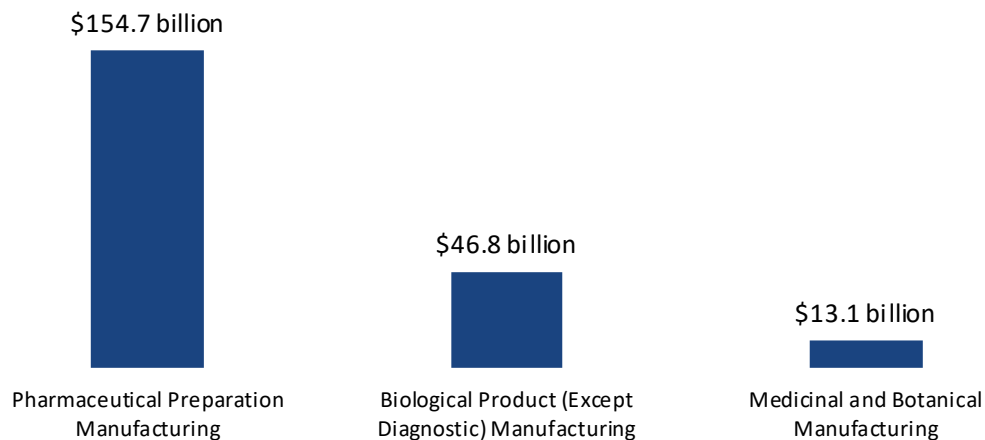
Figure 5: Employment and Payroll for Biopharmaceuticals Subsectors, 2020



Source: [U.S. Census Bureau, Annual Survey of Manufactures](#)

Figure 6 shows the sales, value of shipments, or revenue for each of the Biopharmaceuticals subsectors. Of the three subsectors, Pharmaceutical Preparation Manufacturing had the highest sales, value of shipments, or revenue (approximately \$154.7 billion), followed by Biological Product (Except Diagnostic) Manufacturing (\$46.8 billion).

Figure 6: Sales, Value of Shipments, or Revenue for Biopharmaceuticals Subsectors, 2020



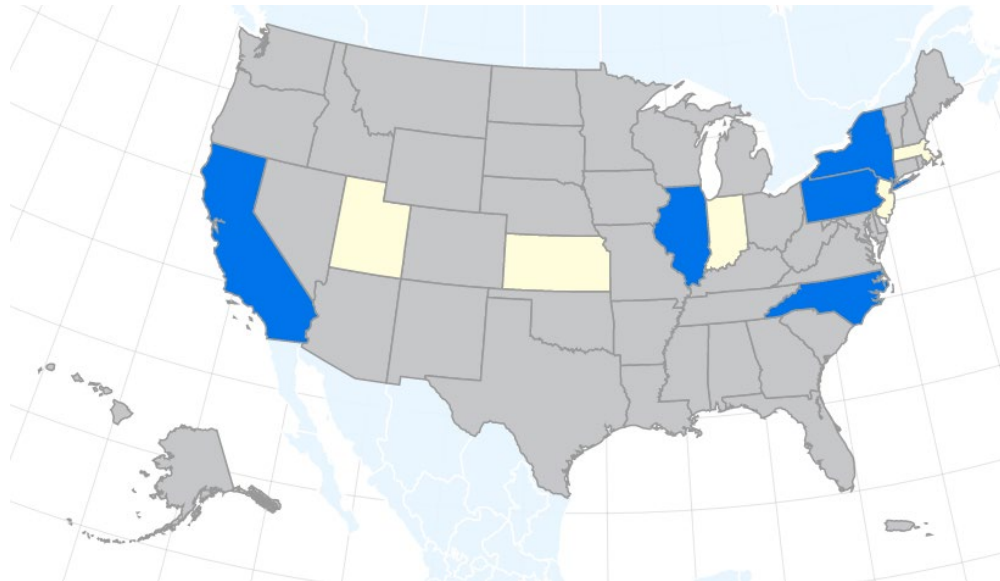
Source: [U.S. Census Bureau, Annual Survey of Manufactures](#)

The U.S. Cluster Mapping Tool presents information on the Biopharmaceuticals cluster (which the resource defines as including the three subsectors highlighted above as well as In-Vitro Diagnostic Substance Manufacturing). In 2019, the Biopharmaceuticals cluster was made up of 2,602 establishments across the United States that employed 263,495 professionals earning an average annual wage of \$100,624.

Figure 7 presents the states that offer high employment specialization and share in the Biopharmaceuticals cluster. California, Illinois, New York, North Carolina, and Pennsylvania offer both high employment specialization and share in this cluster.

Figure 7: Employment Specialization and Share in the Biopharmaceuticals Cluster by State, 2019

■ High Employment Specialization and Share ■ High Employment Specialization ■ High Employment Share



Source: [U.S. Cluster Mapping](#)

Figure 8 presents the establishments, employment, and location quotient for the five states that offer both high employment specialization and share in the Biopharmaceuticals cluster. Of these states, North Carolina has the highest location quotient in the cluster (3.01), while California has the most employees (49,208) and establishments (466).

Figure 8: Employment and Establishments in the Biopharmaceuticals Cluster for States with High Employment Specialization and Share, 2019

State	Location Quotient	Employment	Establishments
North Carolina	3.01	21,547	78
California	1.54	49,208	466
Illinois	1.50	17,099	81
New York	1.41	21,955	141
Pennsylvania	1.38	14,928	87

Source: [U.S. Cluster Mapping](#)

For more on the Biopharmaceuticals cluster, more granular information (including data specifically on the Biopharmaceutical Products subcluster, the Biological Products subcluster, and the Diagnostic Substances subcluster) is available on the [U.S. Cluster Mapping Tool's website](#).

Foreign Direct Investment in Pharmaceuticals

BEA's FDI data is available for the Pharmaceuticals and Medicines Manufacturing industry (NAICS 3254), which represents the three Biopharmaceuticals industry subsectors as well as In-Vitro Diagnostic Substance Manufacturing (NAICS 325413).

BEA estimates that in 2020, the inward position of FDI in the Pharmaceuticals and Medicines Manufacturing industry in the United States was \$545.5 billion. Majority foreign-owned companies in the industry directly supported 215,100 U.S. jobs as of 2019.

According to fDi Markets, from December 2016 to November 2021, companies announced 223 greenfield foreign direct investment projects in the Pharmaceuticals sector with an estimated capital expenditure of \$10.0 billion and supporting an estimated 23,234 jobs.

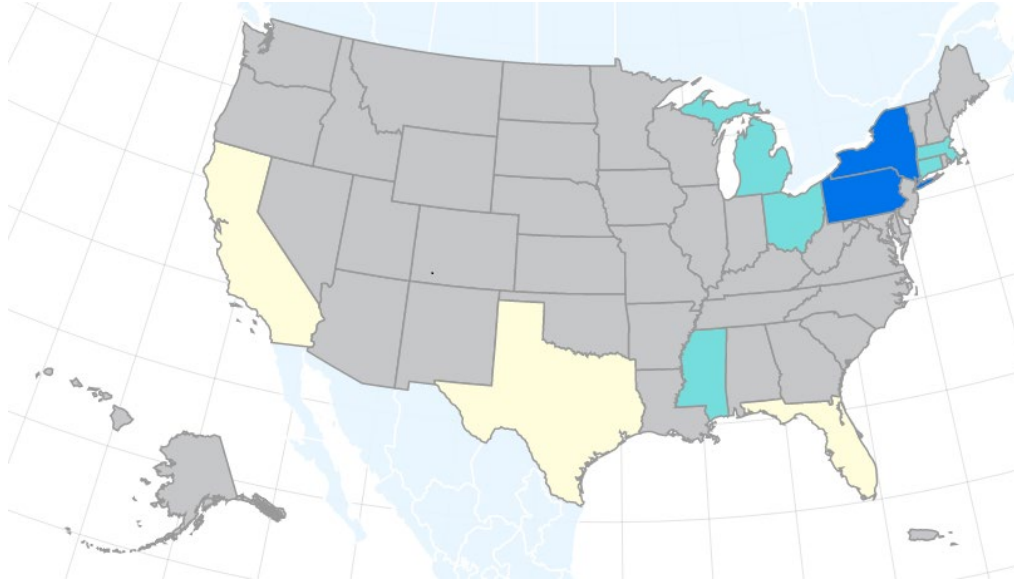
Local Health Services

The Local Health Services cluster encompasses healthcare providers across the United States. Areas that offer high employment specialization and share in the Local Health Services cluster may be useful for investors to consider, as they may be correlated with high concentrations of potential consumers and business opportunities for the Medical Devices and Biopharmaceuticals industries. The Local Health Services cluster represents a variety of subclusters such as Hospitals, Medical Laboratories, Healthcare Provider Offices, Drug Stores, and Medical Equipment Distribution and Rental.

Figure 9 presents the states in the Local Health Services cluster with high employment specialization and share in 2019. According to the Cluster Mapping Tool, New York and Pennsylvania offer both high employment specialization and share in the Local Health Services cluster. Meanwhile, California, Florida, and Texas offer high employment share. Connecticut, Massachusetts, Michigan, Mississippi, and Ohio offer high employment specialization.

Figure 9: Employment Specialization and Share in the Local Health Services Cluster by State, 2019

■ High Employment Specialization and Share ■ High Employment Specialization □ High Employment Share



Source: [U.S. Cluster Mapping](#)

Figure 10 presents the establishments, employment, and location quotient in the Local Health Services cluster for the states that offer high employment specialization and/or share. Of these 10 states, Pennsylvania has the highest location quotient (1.19), while California has the most employees (1,816,579) and establishments (104,077).

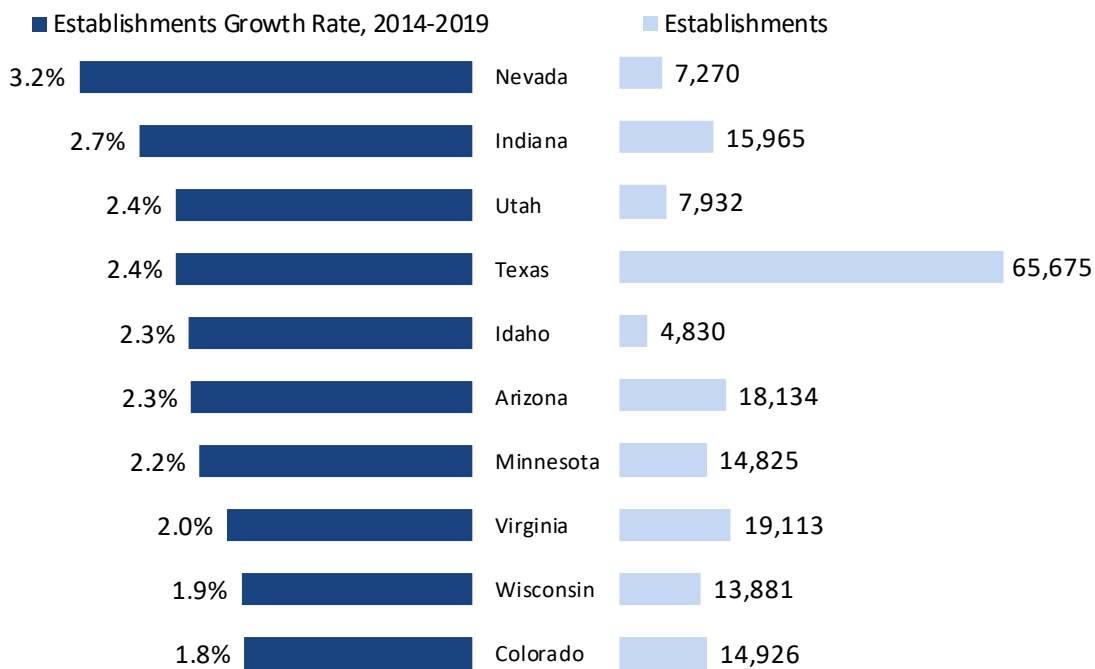
Figure 10: Employment and Establishments in the Local Health Services Cluster for States with High Employment Specialization and/or Share, 201

State	Location Quotient	Employment	Establishments
Pennsylvania	1.19	918,365	33,335
Massachusetts	1.17	530,161	16,796
Connecticut	1.16	245,159	10,164
Ohio	1.15	769,317	26,407
New York	1.14	1,418,357	53,101
Mississippi	1.14	157,985	5,947
Michigan	1.10	586,362	25,757
Florida	0.95	1,093,710	59,814
Texas	0.91	1,379,288	65,675
California	0.87	1,816,579	104,077

Source: [U.S. Cluster Mapping](#)

Figure 11 presents the top 10 states by the five-year historical growth rate of establishments in the Local Health Services cluster as well as the total number of establishments in 2019. Nevada had the highest establishment growth rate in the cluster (3.2 percent), followed by Indiana (2.7 percent). Of these 10 states, Texas had the most establishments in 2019 (65,675).

Figure 11: Top 10 States by Growth Rate of Establishments in the Local Health Services Cluster, 2019



Source: [U.S. Cluster Mapping](#)

Regulators

Food and Drug Administration (FDA)

The [Food and Drug Administration](#) (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices in the United States.

Center for Devices and Radiological Health (CDRH)

The FDA's [Center for Devices and Radiological Health](#) (CDRH) regulates firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States. In the United States, medical devices are classified as Class I, II, or III devices. The classification determines and defines the appropriate regulatory requirements with regulatory control increasing from Class I to Class III.

Manufacturers of medical devices distributed in the United States must comply with regulatory requirements, including but not necessarily limited to the following:

- [Establishment Registration](#)
- [Medical Device Listing](#)
- [Premarket Notification 510\(k\)](#), unless exempt, or [Premarket Approval](#) (PMA)
- [Investigational Device Exemption \(IDE\) for Clinical Studies](#)
- [Quality System \(QS\) Regulation](#)
- [Labeling Requirements](#)
- [Medical Device Reporting \(MDR\)](#)

Center for Drug Evaluation and Research (CDER)

The FDA's [Center for Drug Evaluation and Research](#) (CDER) regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. CDER evaluates and approves new drugs before they enter the market. Companies seeking to sell a drug in the United States must test and send CDER the evidence from these tests to prove the drug is safe and effective for its intended use. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the company's data and proposed labeling.

Center of Biologics Evaluation and Research (CBER)

The FDA's [Center of Biologics Evaluation and Research](#) (CBER) regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. CBER also provides the public with information to promote the safe and appropriate use of biological products.

SelectUSA

This report is intended as a starting point for your business investment in the United States. SelectUSA is available to help you continue to pursue your investment with a variety of free services for firms, which include:

- Information on the competitive and regulatory landscape in the United States, industry, and [workforce data](#)
- Resources on establishing and operating a business in the United States
- Information on federal business incentives, grants, loans, and other programs
- Introductions to economic development organizations
- Ombudsman services to help investors address issues involving federal rules, regulations, programs, or activities related to existing, pending, and potential investments

In addition, [Trade.gov/SelectUSA](#) provides a wealth of information on SelectUSA's services, as well as other information related to foreign direct investment in the United States. Among these online resources is [SelectUSA Stats](#), a set of interactive dashboards including a [workforce data analysis](#) tool that provides specific occupational data for U.S. states and metropolitan areas. SelectUSA.gov also contains contact information so that you can get in touch and stay connected with SelectUSA.

Definitions

Cluster – A cluster is a regional concentration of related industries that arise out of the various types of linkages or externalities that span across industries in a particular location.

Establishment – An establishment is a single physical location at which business is conducted or services or industrial operations are performed. It is not necessarily identical with a company or enterprise, which may consist of one or more establishments. When two or more activities are carried on at a single location under a single ownership, all activities generally are grouped together as a single establishment.

High Employment Share – Areas with high employment *share* rank among the top 10 percent of areas with employment information by number of employees in an industry.

High Employment Specialization – Areas with high employment *specialization* have a location quotient ranking among the top 25 percent of areas with employment information for an industry.

Location Quotient (LQ) – The LQ value is the ratio of an industry’s share of total area employment relative to its share of total national employment. An LQ value greater than 1 indicates a higher than average cluster concentration in a location.

North American Industry Classification System (NAICS) – The standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy.

Sales, Value of Shipments, or Revenue – All appropriate dollar volume measures including total sales, value of shipments, revenue, receipts, or business done at any time during the census year, whether or not payment was received during the census year.

Sources

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About SelectUSA

SelectUSA is a U.S. government-wide program housed in the International Trade Administration at the United States Department of Commerce. Our mission is to facilitate job-creating business investment into the United States and raise awareness of the critical role that economic development plays in the U.S. economy.



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